

OFFICE OF SPECIAL MASTERS

October 30, 2002<sup>1</sup>

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ANGELA COLOSI as Parent and Natural  
Guardian of STEPHANIE COLOSI, a minor

Petitioner,

v.

SECRETARY OF THE DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

Respondent.

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No. 02-310V  
PUBLISHED

I. Keith McCarty, Charleston, SC, for petitioner.  
Gregory W. Fortsch, Washington, DC, for respondent.

**DECISION**

**MILLMAN, Special Master**

Petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, et seq., on April 12, 2002, alleging that her daughter Stephanie Colosi (hereinafter

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<sup>1</sup> This decision was initially issued unpublished on September 30, 2002, but on motion of respondent, it is being reissued in published form.

“Stephanie”) developed intussusception because of her receipt of Rotashield vaccine on April 12, 1999.<sup>2</sup>

On April 15, 2002, petitioner filed Exhibit 11, an affidavit from Dr. Anna C. Pruitt, who was Stephanie’s treating physician. She opined that she saw Stephanie on March 28, 1999 at the Roper ER because Stephanie had a fever of 103 degrees and her stools were green. A stool sample revealed that she had Rotavirus infection. Pruitt affidavit at ¶ 5.

Dr. Pruitt stated that Stephanie received Rotashield vaccine on April 12, 1999. Pruitt affidavit at ¶ 6. Between April and June 1999, Stephanie was seen several times for upper respiratory infections. On June 3, 1999, she was in good health for her four-month check-up. Pruitt affidavit at ¶ 7.

Dr. Pruitt saw Stephanie on August 2, 1999, which was over three months after her receipt of Rotashield vaccine. Stephanie had been vomiting and had diarrhea. Dr. Pruitt diagnosed intussusception. Surgery was performed after a barium enema was only partially successful. Dr. Pruitt opined that Stephanie’s Rotashield vaccination probably caused her intussusception. Pruitt affidavit at ¶¶ 8, 9, and 11. Dr. Pruitt did not give any basis for her opinion.

On July 11, 2002, respondent filed his Rule 4(b) Report, denying that Rotashield caused Stephanie’s intussusception, with four medical articles in support of his position. The first article, “Possible Association of Intussusception With Rotavirus Vaccination,” American Academy of

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<sup>2</sup> Intussusception is a Table injury for rotavirus vaccine if it occurs within 0 - 30 days after receipt of the vaccine as long as the vaccination was administered on or before August 26, 2002. 67 Fed. Reg. 48558 (July 25, 2002), adding a new paragraph to the Vaccine injury table, section 100.3 (a) XII and (c) (3). See 2002 WL 1676386, at \*6 (F.R.). Stephanie received her vaccination before intussusception was taken off the Vaccine injury table, but her onset of intussusception occurred after the table limits, making this a causation in fact case.

Pediatrics, 104 *Ped* 3:575 (1999), states that there may be an increased risk of intussusception during the first few weeks after receipt of Rotashield vaccine. R. Ex. A. The second article, "Population-based study of rotavirus vaccination and intussusception," by P. Kramarz, et al., 20 *Ped Infect Dis J* 4:410-16 (2001), states that the greatest risk of intussusception caused by rotavirus vaccine is within 3 to 7 days after the first dose. R. Ex. B. The third article, "Intussusception Among Recipients of Rotavirus Vaccine: Reports to the Vaccine Adverse Event Reporting System," by L.R. Zanardi, et al., 107 *Ped* 6 (June 2001) ([www.pediatrics.org/cgi/content/full/107/6/e97](http://www.pediatrics.org/cgi/content/full/107/6/e97)), states that in the first week after rotavirus vaccination, there was at least a fourfold increase over the expected number of intussusception cases. R. Ex. C. The fourth article, "Intussusception Among Infants Given an Oral Rotavirus Vaccine," by T.V. Murphy, et al., 344 *New Eng J Med* 8:564-72 (2001), states that there is an increased risk of intussusception 3 to 14 days after the first dose of rotavirus vaccine. The risk of intussusception after the second dose of vaccine was smaller. R. Ex. D.<sup>3</sup>

In a telephonic status conference on August 10, 2002, petitioner's counsel advised the undersigned and respondent's counsel that Dr. Pruitt preferred not to testify in this case. Petitioner's counsel had contacted Dr. Paul M. Darden, Professor of Pediatrics and Biometry and Epidemiology at the Medical University of Charleston, SC, who has tested Rotashield virus.

On September 16, 2002, in a telephonic status conference, petitioner's counsel advised the undersigned and respondent that his expert, Dr. Darden, had given him an unfavorable report in this case. The undersigned requested a copy of Dr. Darden's report, dated September 16, 2002, which counsel provided with an accompanying letter dated September 18, 2002. (These materials are appended to this Order and are filed by leave of the Court.)

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<sup>3</sup> Respondent's Exhibit E contains a correction page for this article.

Using his epidemiological analysis, Dr. Darden stated that the interval of 3 months and 18 days between Rotashield vaccination and onset of intussusception in Stephanie's case meant that it was unlikely that the vaccination had caused her illness.

## **DISCUSSION**

Petitioner is proceeding on a theory of causation in fact. To satisfy her burden of proving causation in fact, petitioner must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioner must not only show that but for the vaccine Stephanie would not have had the injury, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

Dr. Pruitt opined that Rotashield vaccine caused Stephanie's intussusception, but did not give any basis for her opinion. Her affidavit does not satisfy petitioner's evidentiary burden. She has refused further involvement in this case.

Dr. Darden, who seems eminently qualified to give an opinion as a professor in pediatrics, biometry and epidemiology, opined that the interval of time between vaccination and illness was too

long to attribute causation to the Rotashield vaccine. The medical literature that respondent filed is consistent with Dr. Darden's opinion.

Petitioner has failed to make a prima facie case of causation in fact and this case must be dismissed.

**CONCLUSION**

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.

**IT IS SO ORDERED.**

DATED: \_\_\_\_\_

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Laura D. Millman  
Special Master